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AUTOMATIC LEAKAGE CURRENT MEASUREMENT METHOD AND THRESHOLD DECISION FEATURE OF IEC 62353:2014

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ABSTRACT

Electrical safety testing is a very important activity to ensure safe operating standards for every product that uses electricity, especially medical devices. IEC 62353:2014 is used as standard for periodic and after repair testing on electromedical equipment. There are three methods, namely alternative methods, differential methods and direct methods. However, there are still many electromedical practitioners who have difficulty deciding which method will be used when conducting electrical safety testing on a certain medical device. Therefore, an automatic leakage current measurement method and threshold decision feature of IEC 62353:2014 is developed. The development is implementing the method decision flow chart in appendix of IEC 62353:2014 document in google spreadsheet platform.

Keywords: electrical safety testing, leakage current measurement method, electrical threshold

INTRODUCTION

Electrical safety testing is a very important activity to ensure safe operating standards for every product that uses electricity, especially medical devices. The risk of electric leakage in medical devices, especially those directly connected to patients, can increase the risk of electric shock [1-2]. Electrical safety systems in hospitals, medical devices that use electricity carry out controls at least once a year. If you do not carry out electrical safety checks, there is a possibility of leakage current in the medical device and pose a risk to the patient [3-5]. Performing an electrical safety test will ensure that the medical device is in good condition and has no current leakage.

IEC 62353:2014 is used as a standard for the periodic testing and after repair of electromedical equipment. There are three methods, namely alternative methods, differential methods and direct methods [4]. There is a flow chart of what methods to use and steps for electrical safety testing. Currently there are still many electromedical practitioners who have difficulty determining which method to use when conducting electrical safety tests on certain medical devices.

Electrical safety measurements using an electrical safety analyzer. In ESA there are standards used such as IEC 62353:2014, IEC 60601-1, NFPA-99[7].Therefore, to give guidance and accelerate the process of electrical safety testing for electromedical practitioners to determine which method to use, an automatic leakage current measurement feature and an IEC 62353:2014 threshold decision have been developed. By implementing the method decision flowchart in the attached document IEC 62353:2014 on the Google Spreadsheet platform. With the development of the Automatic Leakage Current Measurement Method and the IEC 62353:2014 Threshold Decision Feature it can be used as a teaching method in lectures

RESEARCH METHODS

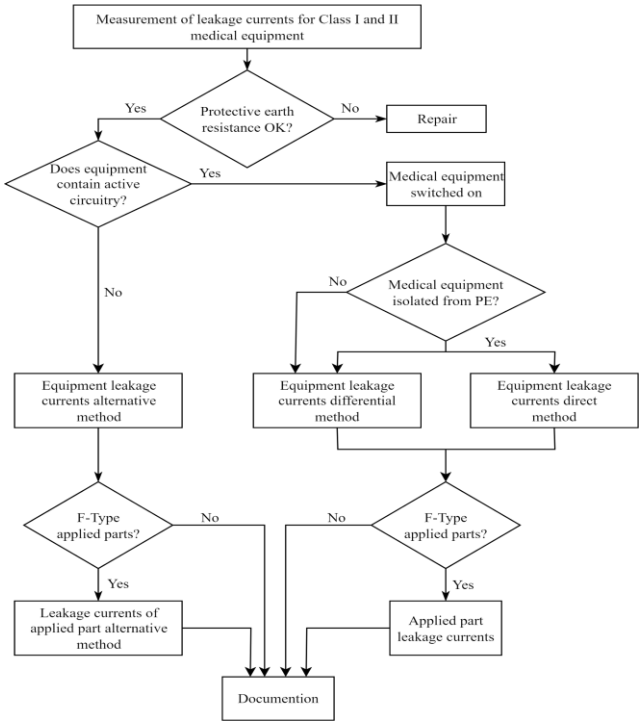

Figure 1. Flowchart

Leakage current measurement for class I and class II medical equipment. The first determines the resistance of the protective grounding. If No do repairs and Yes next steps. In the next step, does the equipment contain active circuits? If No, perform an alternative Equipment leakage current method. and if Yes, was the medical equipment turned on. Next, medical equipment isolated from PE? If not available, perform the equipment leakage current differential method. and if Yes, apply the direct equipment leakage current method. Next up, the F-Type? If No, do Documentation. And if Yes, Apply the last part leakage current and documentation. In the alternative method of leakage current equipment, the next applied part is the F-Type? If not, do

the documentation. And if yes, do the leak current from the part alternative method implemented and finally the documentation.

Review On Standard Documents

In Indonesia to get iec 62353, you can go through the SNI Access website by first registering an account and then logging back into that account. Then it can be searched with the search word 62353. In this study the data used in the IEC 62353 flowchart method of measuring leakage currents and leakage current limits in various parts of the application are in accordance with Table and Formula Development

Table 1. Leakage current limits in different application parts according to IEC 62353:2014

Current in microampere	**Application part**		
	B (µA)	BF (µA)	CF (µA)
Equipment leakage (alternative method)			
Class I	1000	1000	1000
Class II	500	500	500
Equipment leakage(direct or differential method)			
Class I	500	500	500
Class II	100	100	100
Patient leakage (alternative method)			
Class I and Class II		5000	50
Patient leakage (direct method)			
Class I and Class II		5000	50

In table 1 carrying out electrical safety tests follow the IEC 62353:2014 procedure. There is a threshold value determined based on each method, type class, and part of the application. In microamperes on equipment leakage (alternative method), Class I Type B 1000, Type BF 1000 and CF 1000. Class II Type B 500, Type BF 500 and CF 500. In equipment leakage (direct or differential method), Class I Type B 500, Type BF 500 and CF 500. Class II Type B 100, Type BF 100 and CF 100. The patient leakage (alternative method). Type BF 5000 and CF 50. And the patient is leakage (direct method). Type BF 5000 and CF 50.

RESULTS AND DISCUSSION

Input, output and results are done through google spreadsheets that have been formulated

Table 2. Input

Class	Protective Earth Resistance	Active Circuitry	Isolated From PE	F-Type	Power Supply
I	Available	Yes	Yes	B	Permanent Installation
II	Not Available	No	No	BF	Non- detachable Power Supply
				CF	Detachable Power Supply
					Multiple Contacts System

In table 2 is the input on google spreadsheet which consists of Class, Protective Earth Resistance, Active Circuitry, Isolated From PE, F-Type and Power Supply. in class I and II. Earth Resistance Shield available and unavailable. PE Active and Isolated Circuits have Yes and No. Type-F there are B, BF and CF. There Are Permanent Installation Power Supplies, Non-Removable Power Supplies, Removable Power Supplies, and Multiple Contact Systems

Table 3. Output

equipment leakage current method	applied part leakage current method	protective earth resistance limit	equipment leakage current limit						applied part leakage current limit	
			Class I			Class II				
			B	BF	CF	B	BF	CF	BF	CF
alternative	alternative	300	1000	1000	1000	1000	1000	500	5000	50
differential	differential	300	500	500	500	100	100	100		
direct	not available	300	500	500	500	500	100	100	5000	50
		500								

In table 3 is the output on google spreadsheet which consists of the Equipment leakage current method, Applied part leakage current method, Protective earth resistance limit, Equipment Leakage Current Limit and Applied part leakage current limit. Equipment leakage current limit Class I with alternative method type B, BF and CF score 1000. The differential type B, BF and CF score 500. And Direct type B, BF and CF score 500. On class II with

alternative method type B and BF score 1000 for type CF 500. Differential method type B, BF and CF score 100. And direct method type B score 500 and type BF and CF 100.

RESULT

In table 4 is the result of google spreadsheet. Class I, protective earth resistance Available, active circuitry No, isolate form PE No, F-type CF, power supply Permanent Installation, equipment leakage current method Alternative, applied part leakage current method Alternative, protective earth resistance limit 300, equipment leakage current limit 1000, and applied part leakage current limit 50

Tabel 4. Result

class	protective earth resistance	active circuitry	isolated from PE	F-type	power supply	equipment leakage current method	applied part leakage current method	protective earth resistance limit	equipment leakage current limit	applied part leakage current limit
I	Available	No	No	CF	Permanent installation	alternative	alternative	300	1000	50
I	Available	Yes	No	BF	Non-detachable power supply	differential	differential	300	500	5000
I	Available	Yes	Yes	B	Multiple contacts system	direct	not available	500	500	50

CONCLUSION

After the formulation is made in Google Sheets, the results are obtained by clicking on the available options. There are two types of classes, Class I and Class II. protective earth resistance, Available or Not Available. active circuit; Yes or no. isolated from PE; Yes or no. F-type; B, BF or CF. power supply; Permanent Installation, Non-Removable Power Supply, Removable Power Supply and Multiple Contact System.

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